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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/286,189	08/05/94	SANHUEZA S	MCM510.2348

HM11/0213

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EXAMINER	
NELSON,E	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/13/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/286,189	Applicant(s) Sanhueza, et al.
	Examiner Brett Nelson	Group Art Unit 1648

☒ Responsive to communication(s) filed on *Apr. 23, 1997 (see Office Action 1st. par.)* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

2. The amendment filed Apr. 23, 1997 is being treated under 35 U.S.C. 132 as a request for reconsideration. Applicant has prematurely filed the Notice of Appeal and the Appeal Brief without allowing the reexamination to take place. Furthermore, the Brief includes the amended claims submitted in the Apr. 23, 1997 amendment, which claims, by virtue of the amendments have never been examined and therefore can not now be appealed. Applicant is entitled to a refund for any fees paid for the Notice of Appeal and Appeal Brief. Claims 17-19 were canceled as per amendment date Apr. 4, 1996. Claims 2 and 10 were canceled as per amendment date Apr. 23, 1997. Claims pending and under consideration are claims 1, 3-9, and 11-16.

3. All previous rejections have been withdrawn in view of the amendments to the claims.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

4. Claims 1, 3-9, and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The claims are drawn to read on vaccines and methods of preparing vaccines for respiratory syncytial virus (RSV). The specification shows inactivated RSV, which has been inactivated by n-octyl-β-D-glucopyranoside, β-propiolactone, or ascorbic acid, and which elicits antibody production in cotton rats.

The specification provides no probative evidence to support the claimed vaccine which would protect humans against RSV. In order to enable claims to drugs and their uses, either in vivo or in vitro data, or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the claims are sufficiently enabled. When the claims are directed to humans adequate animal data would be acceptable in those instances wherein one of ordinary skill in the art would accept the correlation to humans. Thus in order to rely on animal data there must exist an art-recognized animal model for testing purposes. See In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962). The instant application employs the cotton rat as a model for testing the composition. However, Hildreth et al. (Vaccine 1993) state that the cotton rat model has significant limitations as a model for RSV because rats do not have clinical signs associated with RSV infection and, as expected, the lungs of RSV-infected rats lack a corresponding severity of pulmonary inflammation. The significant variability in the minimum histological changes observed with this outbred laboratory animal results in the need for highly reproducible morphometric procedures. Hildreth et al. also state that the cotton rat model creates a biological system that applies too much importance to small differences in outcomes from any given immunogen (p. 618). Additionally, Hall (Science 1994) states "Currently there is no

accurate way to predict the response of infants to a candidate vaccine before actual administration" and "We do not even know what type of immune response would be safe and protective in young infants" (P. 1394). Hall also states that children vaccinated with an inactivated vaccine were not only susceptible to infection but many develop severe lower respiratory tract infection and some cases even death (p. 1393). Finally, Toms (Archives of Disease in Childhood 1995) states that protection of animals in the laboratory is much more easily achieved than protection of infants against natural infection (p. 2). By definition vaccines must not only induce an immune response, but must be immunogenic to the extent that upon subsequent challenge with the live virus, development of the disease is prevented, or better yet infectivity does not occur. Therefore, it appears that the cotton rat data does not correlate to humans and the cotton rat is not an art accepted model for vaccine evaluation with regards to RSV in humans and particularly infants.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ 2d 1400 at 1404 (CAFC 1988). In the instant specification, it is determined that: 1) there are no working examples which suggest the desired results of a vaccine against RSV, 2) the nature of the invention involved the complex and incompletely understood area of immunity to RSV, 3) the state of the prior art shows that prior vaccines and treatment methods have been largely ineffective for the intended purpose, 4) the relative skill of those in the art is commonly

recognized as quite high (post-doctoral level), and 5) the lack of predictability in the field to which the invention pertains is recognized in the art as evidenced by prior failures.

Therefore, in view of all of the above, it is determined that it would require undue experimentation to practice the invention as claimed.

5. Claims 1, 3-9, and 11-16 appear to be free of the prior art. However, should the claims be amended to remove the vaccine for human hosts limitations, the claims would be rejectable over the prior art.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)-305-7939. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG

30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Primary Examiner Lynette Smith whose telephone number is (703) 308-3909 or Supervisory Patent Examiner Donald E. Adams whose telephone number is (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NELSON/bn
February 11, 1998

LYNETTE F. SMITH
PRIMARY EXAMINER
GROUP 1800